

PPE AID NITRILE GLOVES

- 510K CERTIFIED
- FDA APPROVED
- EXAM GRADE
- POWDER FREE





**Test Report**

No.: SHHL1602075368MD-01

Date: OCT. 06, 2020

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SHUIAZHUANG HONGRAY GROUP CO., LTD

SOUTH TONGDA RD., EAST DIST. JINZHOU CITY, HEBEI, 052260, CHINA

THE TEST REPORT IS TO SUPERSEDE THE TEST REPORT No.: SHHL1602075368MD

DATE: SEP. 28, 2020

The following sample(s) was/were submitted and identified by the client as:

Sample Description : DISPOSABLE NITRILE GLOVE
 Style/ Item No. : XS,S,M,L,XL,XXL
 Country of Origin : CHINA
 Sample Receiving Date : AUG. 29, 2020
 Testing Period : AUG. 29, 2020 TO SEP. 28, 2020
 Test Performed : SELECTED TEST(S) AS REQUESTED BY APPLICANT
 Test Requested : 1. EN 455-1:2000 MEDICAL GLOVES FOR SINGLE USE –
 PART 1: REQUIREMENTS AND TESTING FOR FREEDOM
 FROM HOLES
 2. EN 455-2: 2000 MEDICAL GLOVES FOR SINGLE USE –
 PART 2: REQUIREMENTS AND TESTING FOR PHYSICAL
 PROPERTIES
 3. EN 455-3: 2000 MEDICAL GLOVES FOR SINGLE USE—
 PART 3: REQUIREMENTS AND TESTING FOR BIOLOGICAL
 EVALUATION CLAUSE 4.4 & 4.5

Test Result(s) : FOR FURTHER DETAILS, PLEASE REFER TO THE
 FOLLOWING PAGE(S)

Conclusion : THE SUBMITTED SAMPLE MET THE TEST REQUIREMENT.

Signed for and on behalf of
 SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd.

Vincent Feng
 Technical Manager



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T (86) 400 960 9881

F (86-21) 6113 0880

www.sgs.com.cn

中國·上海·浦東區雲山路888號4樓 郵政: 200023

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Test Conducted:

1. EN 455-1:2000 Medical gloves for single use – part 1: Requirements and testing for freedom from holes

Number of test sample : 200 Pieces
 The type of gloves : examination/procedure gloves
 Manufacturing batch code : /
 Batch size : /
 Sample size : XS, S, M, L, XL, XXL
 Number of non-conforming gloves : None
 Defects observed before testing : No defects
 Test Result : Pass

Clause	Test Items	Result	Note
5	Watertightness test for detection of holes	---	---
5.1	Referee testing		# 1&2

2. EN 455-2: 2000 Medical gloves for single use – part 2: Requirements and testing for physical properties

Number of test sample : 104 Pieces
 Type : examination/procedure gloves
 The manufacturing batch code : /
 Size : XS, S, M, L, XL, XXL
 Defects observed before testing : No defects
 Test Result : Pass

Clause	Test Items	Result	Note
4	Dimensions	Pass	#3
5	Strength	Pass	#1&4
7	Labeling	Pass	/



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3. EN 455-3: 2000 Medical gloves for single use—Part 3: Requirements and testing for biological evaluation

Number of test sample : 5 Pieces
 Finishes of gloves : Powdered-free gloves other than surgeon's gloves
 Defects observed before testing : No defects
 Test Result : Pass

Clause	Test Items	Result	Note
4.4	Powder	Pass	#1, 5&6
4.6	Labeling	Pass	/

Note:

- As per client's declare, these gloves (four size: XS, S, M, L, XL, XXL) only size different, the material is the same, and only the glove of size M was tested.
- See result 1.
- See result 2.
- See result 3.
- Test according to EN ISO 21171-2006.
- The powder of sample was 0.3mg<2mg.



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Building No. 308, Yuhai Road, Pudong District, Shanghai, China 200233
 中国·上海·浦东新区宣山路308号4号楼 邮编: 200233

Tel: (86-400) 960 9661 Fax: (86-21) 6115 0969 www.sgs.com.cn
 Tel: (86-400) 960 9661 Fax: (86-21) 6115 0969 sgs.china@sgs.com

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Size	XL												
Length(mm)	249	248	250	249	247	248	249	248	248	249	248	249	248
Width(mm)	114	113	114	115	113	114	115	115	114	115	116	114	115

Median value:

Length (mm): 248

Width (mm): 114

Size	XXL												
Length(mm)	245	246	244	244	245	246	245	246	246	245	245	244	243
Width(mm)	119	118	120	119	118	119	118	120	119	118	119	120	119

Median value:

Length (mm): 245

Width (mm): 119

Requirements: see table 1&2

Table 1 Dimensions for surgical gloves

Size	Median length in mm	Median width in mm
5	≥250	67±4
5.5	≥250	72±4
6	≥260	77±5
6.5	≥260	83±5
7	≥270	89±5
7.5	≥270	95±5
8	≥270	102±6
8.5	≥280	108±6
9	≥280	114±6
9.5	≥280	121±6

Table 2 Dimensions for
examination/procedure gloves

Size	Median length in mm	Median width in mm
Extra small	≥240	≤80
Small		80±10
Medium		95±10
Large		110±10
Extra Large		≥110



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Tel: (86) 430 980 9881

F: (86-21) 6115 5886

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F: (86-21) 6115 5886

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3. Strength

Sample Quantity: 26pcs

Size	M												
Force at break(N)	9.19	8.79	9.27	9.02	8.25	9.35	9.27	9.36	8.98	8.38	9.02	8.90	9.58
Force at break after challenge testing(N)	9.41	9.50	9.50	9.38	9.58	9.46	9.23	9.38	9.77	9.50	9.58	9.18	9.65

Median value:

Force at break during shelf life (N): 9.02

Force at break after challenge testing (N): 9.50

Table 3 — Median values of force at break

	Force at break in Newton		
	Surgical gloves a)	Examination/procedure gloves b) c)	
Throughout shelf life tested according to 5.2 and within 12 months of manufacture tested according to 5.3	≥ 9.0	≥ 6.0	≥ 3.6
a) Requirements for all surgical gloves. b) Requirements for all examination gloves, except gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene). c) Requirements for gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene).			

Remark:

- The sample selecting amount for Water-tightness test for detection of holes is deviated to 200 pcs as accessed by SGS.



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Sample Photo:

Received sample (size XS)



Received sample (size S)



Received sample (size M)



Received sample (size L)



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Received sample (size XL)



Received sample (size XXL)



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End of Report



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November 30, 2018

Beijing Plastic Technology Co., Ltd
 Beijing, China
 Project Manager
 Beijing Plastic Technology Co., Ltd
 3973 Schaefer Avenue, Chino, CA 91810, USA

Re: K182600
Trade/Device Name: Powder Free Nitrile Examination Glove, Tested for Use with Chemotherapy Drugs (Blue)
Regulation Number: 21 CFR 880.6250
Regulation Name: Non-Powdered Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA, LZC
Dated: September 16, 2018
Received: September 21, 2018

Abstract

We have reviewed your premarket notification of intent to market the device referenced above and have determined that your device meets substantially all the requirements for the indications for use stated in the enclosure (enclosure) to legally marketed predicate devices manufactured on or after the enactment date of the Medical Device Amendments, or to devices that were marketed in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cddocs/cfp/pmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

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K182600 - Kathy Liu

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statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/Reports/problems/default.htm>.

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